

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich, Karen Fu,  
Jeffrey S. Hrkach, Wen-I Li, Michael M. Lipp, Mei-Ling Pan and Jason Summa

Application No.: Group Art Unit:

Filed: Examiner:

Confirmation No.:

Title: INHALABLE EPINEPHRINE

Date: June 26, 2003 Express Mail Label No.: ER 142989950 US

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed.
  - ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account \_\_\_\_\_ in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

ELMORE CRAIG, P.C.

By

  
Anne I. Craig

Registration No.: 32,976

Telephone: (978) 251-3509

Facsimile: (978) 251-3973

Chelmsford, MA 01863

Dated: 6/25/03

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| PTO-1449 REPRODUCED<br><br><b>INFORMATION DISCLOSURE CITATION<br/>IN AN APPLICATION</b><br><br>(June 24, 2003)<br><br>(Use several sheets if necessary) | ATTORNEY DOCKET NO.<br>2685.2046-003 |                  | APPLICATION NO. |  |
|   | APPLICANT<br>Richard P. Batycky      |                  |                 |  |
|   | FILING DATE                          | CONFIRMATION NO. | GROUP           |  |

## U.S. PATENT DOCUMENTS

| EXAM-<br>INER<br>INI-<br>TIAL | REF.<br>NO. | DOCUMENT NUMBER | ISSUE DATE /<br>PUBLICATION DATE | NAME                      |
|-------------------------------|-------------|-----------------|----------------------------------|---------------------------|
|                               | AA          | 4,352,789       | 10-05-1982                       | Thiel                     |
|                               | AB          | 4,959,358       | 09-25-1990                       | Carey <i>et al.</i>       |
|                               | AC          | 5,002,973       | 03-26-1991                       | Zelevnick <i>et al.</i>   |
|                               | AD          | 5,049,389       | 09-17-1991                       | Radhakrishnan             |
|                               | AF          | 5,655,523       | 08-12-1997                       | Hodson <i>et al.</i>      |
|                               | AF          | 5,738,865       | 04-14-1998                       | Baichwal <i>et al.</i>    |
|                               | AG          | 5,770,559       | 06-23-1998                       | Manning <i>et al.</i>     |
|                               | AH          | 6,076,522       | 06-20-2000                       | Dwivedi <i>et al.</i>     |
|                               | AF          | 6,098,619       | 08-08-2000                       | Britto <i>et al.</i>      |
|                               | AJ          | 6,119,688       | 09-18-2000                       | Whaley <i>et al.</i>      |
|                               | AK          | 6,126,919       | 10-03-2000                       | Stefely <i>et al.</i>     |
|                               | AA2         | 6,183,782 B1    | 02-06-2001                       | Hallworth                 |
|                               | AB2         | 6,221,398 B1    | 04-24-2001                       | Jakupovic <i>et al.</i>   |
|                               | AC2         | 6,245,339 B1    | 06-12-2001                       | Van Oort <i>et al.</i>    |
|                               | AD2         | 6,284,287 B1    | 04-24-2001                       | Sarlikiotis <i>et al.</i> |
|                               | AE2         | 6,309,671 B1    | 10-30-2001                       | Foster <i>et al.</i>      |
|                               | AF2         | 6,360,743 B1    | 03-26-02                         | Andersson <i>et al.</i>   |
|                               | AG2         |                 |                                  |                           |
|                               | AH2         |                 |                                  |                           |
|                               | AI2         |                 |                                  |                           |
|                               | AJ2         |                 |                                  |                           |
|                               | AK2         |                 |                                  |                           |
|                               | AA3         |                 |                                  |                           |
|                               | AB3         |                 |                                  |                           |
|                               | AC3         |                 |                                  |                           |

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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |   |  |
|--|---|--|
| AR   | Simons, F. E.R. <i>et al.</i> , "Can Epinephrine Inhalations Be Substituted for Epinephrine Injection in Children at Risk for Systemic Anaphylaxis?" <i>Pediatrics</i> 106(5):1040-1044 (2000).                               |  |
| AS   | Gu, X. <i>et al.</i> , "Epinephrine Absorption after Different Routes of Administration in an Animal Model," <i>Biopharm. Drug Dispos.</i> 20:401-405 (1999).   |  |
| AT   | Heilborn, H. <i>et al.</i> , "Comparison of subcutaneous injection and high-dose inhalation of epinephrine - Implications for self-treatment to prevent anaphylaxis," <i>J. Allergy Clin. Immunol</i> 78(6):1174-1179 (1986). |  |
| AU   | Warren, J.B. <i>et al.</i> , "Systemic absorption of inhaled epinephrine," <i>Clin. Pharmacol. Ther.</i> 40(6):673-678 (1986).  |  |
| AV   | Mellem, H. <i>et al.</i> , "Faster and more reliable absorption of adrenaline by aerosol inhalation than by subcutaneous injection," <i>Br. J. Clin. Pharmac.</i> 31:677-681 (1991).  |  |
| AW   | Dahlof, C. <i>et al.</i> , "Systemic absorption of adrenaline after aerosol, eye-drop and subcutaneous administration to healthy volunteers," <i>Allergy</i> 42:215-221 (1987).   |  |
| AX   | Plomley, R.F. and D. Czarny, "Inhaled adrenaline in the treatment of anaphylaxis," <i>Med. J. Aust.</i> 149:564 (1988).   |  |
| AY   | Bullock, K. And J.W. Lightbown, "The Spray-drying of Pharmaceutical Products, Part II. Certain Inorganic Salts," <i>The Chemist and Druggist, CXL</i> :147-148 (Jul-Dec 1943).  |  |
| AZ   | Bullock, K. <i>et al.</i> , "The Spray-drying of Pharmaceutical Products, Part III. Digitalis, Adrenaline and Ascorbic Acid," <i>Year-book of Pharmacy XVI</i> :221-226 (1943).   |  |
| AR2  | EpiPen® Autoinjector (Dey). Physicians' Desk Reference, 56 <sup>th</sup> ed. Montvale, New Jersey, Medical Economic Company, Inc. 2002:1236.  |  |
| AS2  | Simons, F.E.R. <i>et al.</i> , "Epinephrine absorption in children with a history of anaphylaxis," <i>J. Allergy Clin. Immunol.</i> 101(1, part 1):33-37 (1998).  |  |
| AT2  | AAAI Board of Directors, Position Statement, "The use of epinephrine in the treatment of anaphylaxis," <i>J. Allergy Clin. Immunol.</i> 94(4):666-668 (1994).   |  |
| AU2  | Simons, F.E.R., <i>et al.</i> , "Epinephrine absorption in adults: Intramuscular versus subcutaneous injection," <i>J. Allergy Clin. Immunol.</i> 108(5):871-873 (2001).  |  |

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

|  |     |  |
|--|-----|--|
|  | AV2 | Goldberg, A. and R. Confino-Cohen, "Insect sting-inflicted systemic reactions: Attitudes of patients with insect venom allergy regarding after-sting behavior and proper administration of epinephrine," <i>J. Allergy Clin. Immunol.</i> 106(6):1184-1189 (2000). |
|  | AW2 | Korenblat, P. <i>et al.</i> , "A Retrospective Study of Epinephrine Administration for Anaphylaxis: How Many Doses Are Needed?" <i>Allergy and Asthma Proc.</i> 20(6):383-386 (1999).  |
|  | AX2 | Sampson, H.A. <i>et al.</i> , "Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents," <i>New Engl. J. Med.</i> 327:380-384 (1992).  |
|  | AY2 | Neugut, A.I., <i>et al.</i> , "Anaphylaxis in the United States, An Investigation Into Its Epidemiology," <i>Arch. Intern. Med.</i> 161:15-21 (2001).  |
|  | AZ2 | Schwartz, H.J., <i>et al.</i> , "Is unrecognized anaphylaxis a cause of sudden unexpected death?", <i>Clin. Exp. Allergy</i> , 25(9):866-870 (1995).   |
|  | AR3 | Barnard, J.H., "Studies of 400 Hymenoptera sting deaths in the United States," <i>J. Allergy Clin. Immunol.</i> , 58(5):259-264 (1973).  |
|  | AS3 | Kemp, S.F. <i>et al.</i> , "Anaaphylaxis, A Review of 266 Cases," <i>Arch. Intern. Med.</i> 155:1749-1754 (1995).  |
|  | AT3 | Pumphrey, R.S.H., "Lessons for management of anaphylaxis from a study of fatal reactions," <i>Clin. Exp. Allergy</i> , 30:1144-1150 (2000).  |
|  | AU3 | Kaliner, M., "Allergy care in the next millennium: Guidelines for the specialty," <i>J. Allergy Clin. Immunol.</i> 99(6, pt1):729-734 (1997).  |
|  | AV3 | Yunginger, J.W. <i>et al.</i> , "Fatal Food-Induced Anaphylaxis," <i>JAMA</i> , 260(10):1450-1452 (1988).  |
|  | AW3 | Atkinson, T. P. And M.A. Kaliner, "Anaphylaxis," <i>Med. Clin. North Am.</i> 74(4):841-855 (1992).   |
|  | AX3 | McConachie, I. "Anaesthetic dilemmas. Laryngeal oedema following anaphylactic shock," <i>Br. J. Hosp. Med.</i> 47(3):201 (1992).   |
|  | AY3 | Darbar, D. <i>et al.</i> , "Epinephrine-Induced Changes in Serum Potassium and Cardiac Repolarization and Effects of Pretreatment With <i>Propranolol</i> and <i>Diltiazem</i> ," <i>Am. J. Cardiol.</i> 77:1351-1355 (1996).                                      |

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| AZ3  | Barnes, P.J., "Effect of $\beta$ -agonists on inflammatory cells," <i>J. Allergy Clin. Immunol.</i> 104(2, pt 2):S10-S17 (1999).  |  |
| AR4  | Bufarlari, A., <i>et al.</i> , "Comparative Responses to Propofol Anaesthesia alone and with $\alpha_2$ -Adrenergic Medications in a Canine Model," <i>Acta Vet. Scand.</i> 37(2):187-201 (1996).   |  |
| AS4  | <i>British National Formulary</i> , 42:155-157 (Sep 2001).  |  |
| AT4  | Medihaler-Epi (3M Health Care Limited). ABPI Compendium of Data Sheets and Summaries of Product Characteristics. 2 <sup>nd</sup> ed. London: Datapharm Publications Limited 693 (1998-1999).        |  |
| AU4  | Soreide, E. <i>et al.</i> , "Severe anaphylactic reactions outside hospital: etiology, symptoms and treatment," <i>Acta Anaesthesiol. Scand.</i> 32:339-342 (1988).                                 |  |
| AV4  | National Advisory Committee on Immunization (NACI). "Anaphylaxis: Statement on Initial Management of in non-hospital settings," <i>Canada Communicable Disease Report</i> , 21-22:F1-F5 (1995).     |  |
| AW4  | AAAAI Board of Directors, Position Statement, "Anaphylaxis in Schools and Other Child-care Settings," <i>J. Allergy Clin. Immunol.</i> 102(2):173-176 (1998).                                       |  |
| AX4  | Scheuch, G. <i>et al.</i> , "Measuring <i>in vivo</i> deposition of large porous particles," Abstract-138, ISAM, 12 <sup>th</sup> International Congress. <i>J. Aerosol. Med.</i> 12(2):127 (1999). |  |
| AY4  | Sabroe, R.A. <i>et al.</i> , "Therapeutics, An audit of the use of self-administered adrenaline syringes in patients with angio-oedema," <i>British Assoc. Of Dermatology</i> 146:615-620 (2002).   |  |
| AZ4  | Muller, U. <i>et al.</i> , "Withdrawal of the Medihaler-epi®/Adrenaline Medihaler®: comments of the Subcommittee on Insect Venom Allergy of the EAACI," <i>Allergy</i> , 53:619-620 (1998).         |  |
| AR5  | Primatine® Mist (Wyeth). Physicians' Desk Reference, 21th ed. Montvale, New Jersey, Medical Economic Company, Inc., 792 (2000).   |  |
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